

Negative results - Arrhythmia

Wire perforation of Flex 10 microwave device during thoracoscopic atrial fibrillation ablation

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Abstract

Introduction: Rapid advances in technology are increasing the repertoire of techniques available for the surgical treatment of atrial fibrillation (AF). These techniques utilize new devices which are normally safe. However, potential problems can arise with a new device as is illustrated in this report. **Methods:** A 58-year-old man underwent a thoracoscopic AF ablation utilizing the Flex 10 probe (Guidant, Afix, Fremont, CA). **Results:** We experienced an important device failure following thoracoscopic microwave AF ablation that has not been reported to date. **Conclusion:** Although new devices seem to be safe, potential problems often emerge with time, and clinicians pioneering these technologies have an obligation to report these experiences to the wider surgical community.

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1. Introduction

The surgical treatment of atrial fibrillation (AF) has evolved from the traditional complex cut and sew technique described by Cox [1] to more simplified techniques using alternative energy sources. These energy sources delivered in different forms (cryotherapy, radiofrequency, microwave, ultrasound energy) can yield good results [2,3]. Microwave energy in particular can be delivered using flexible probes, that allow easy application during open or minimally invasive AF ablation [4,5]. Microwave energy produces heat injury to the atrial myocardium by causing tissue vibration and rotation of charged dipole water molecules [6]. An increasing number of individual experiences are emerging in the literature, along with novel ways to perform ever more complex concomitant tasks involving obliteration of the left atrial appendage [5,7]. We continue to support the development of these techniques. In the era of clinical governance, however, clinicians are obliged to report negative as well as positive results. We recently experienced device dysfunction of the Flex 10 probe during thoracoscopic lone AF ablation procedure and outline mechanisms for recognition of this previously undescribed but potentially dangerous occurrence.

A 58-year-old man with a 15-year history of paroxysmal AF that had become persistent for the last 12 months was referred for thoracoscopic microwave AF ablation. He had suffered recurrent episodes of transient ischaemic attacks despite warfarin therapy. The protracted history suggested that success of pulmonary vein isolation alone would not

be sufficient to control his arrhythmia but it was decided to proceed with an attempt at surgical ablation in the first instance, followed by mapping and further catheter based ablation as required. Following informed consent, he was taken to theatre. Anaesthesia was administered and intubation with a double lumen endotracheal tube was performed. Transoesophageal echocardiography excluded the presence of thrombus in the left atrial appendage. The patient was placed in the supine position with facility for right and left chest elevation using inflatable fluid infusion bags placed behind each scapula. Following deflation of the right lung three ports were created at the 3rd, 4th and 5th right intercostal spaces for the camera and endoscopic instruments. The pericardium was opened anterior to the right phrenic nerve and the transverse and oblique sinuses were dissected using endopearls (Ethicon). Two nasogastric (NG) tubes were then passed into the sinuses. The tips of both NG tubes were retrieved from the left side of the chest following left lung deflation and opening of the pericardial sac posterior to left phrenic nerve. The NG tubes were then tied together and used as a router for the Flex 10 catheter to encircle all four pulmonary veins. At the time of insertion, the device looked structurally normal. The position of the probe with respect to the left atrial appendage was checked to ensure correct orientation and to exclude malposition into the atrioventricular groove. Sixty-five watts of microwave energy was delivered for 120 s at each station. At all times during the procedure the probe was not held with a forceps to avoid damage. During the ablating procedure there was a subtle and transient difficulty in moving the switch on the black handle of the device from station 5 to station 6. For the remainder

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Fig. 1. Part of the flexible probe component protruding through the probe fascial covering.

of the procedure there were no difficulties and microwave ablation injury was clearly visible along the roof of the left atrium. After complete ablation the probe was withdrawn from the chest and on inspection there was a sharp metallic cable protruding through the fascial covering of the ablating probe (Figs. 1 and 2). Diligent haemostasis and search for any potential bleeding site was undertaken prior to closure over four bilateral chest drains. The patient was discharged on day 4 after making an uneventful postoper-



Fig. 2. Another view of the flexible probe component protruding through the probe fascial covering.

ative recovery. The failure of the probe was reported to the manufacturer immediately after the operation. Detailed examination of the probe demonstrated no abnormality in conformity of the microwave electrode but the protruding metallic cable was noted as a potential hazard. No such device failure has previously been reported.

2. Comment

The Flex 10 device consists of a microwave generator and hand-held probe accessories. The flexible probe of the Flex 10 is connected to a black rigid handle, which mounts the switch that is used to move the flexible antenna inside the probe. For the Flex 10 probe, the manufacturer recommends the delivery of 65-Watt energy for a maximum of 120 s at each station as was performed in this case.

We noted subtle difficulty in moving the switch from station five to station six during the procedure. We believed that this might have heralded breakage of the mechanism that carries the microwave electrode within the probe. The mechanism of this breakage and subsequent breach of the probe's fascial sheath is not known, but it can be easily overlooked during thoracoscopic procedures. The cable is sturdy enough to produce potentially serious injury if not recognized prior to removal. This was fortuitously avoided in this case.

Failure of electrode movement through all of the desired stations may also result in failure of the ablation protocol. We observed tissue injury at stations 1 through to 10 in this case and perform this as a routine in order to avoid this problem.

Clinicians pioneering the use of new technology have an obligation to disseminate potentially hazardous device failure to the wider surgical community. In retrospect, difficulty in moving the electrode from station 5 to 6, although very subtle, was undoubtedly an important indicator of potential device malfunction and, when encountered, should alert the clinician undertaking the procedure so that careful extraction of the probe can be undertaken until device failure can be excluded.

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